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October 22, 1996

E. L. SORENSEN, JR.
Executive Director

Mr. D--- B. F---

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XXX --- ---, Suite XXXX

---, CA XXXXX-XXXX

SR -- XX-XXXXXX

C--- C---, Inc.

Endovascular Catheter

Dear Mr. F---:

I am answering your letter to me dated August 22, 1996. You request advice on the application of sales and use tax to the Medtronic AneuRx Endovascular Prosthesis & Delivery Catheter. You ask if the item qualifies as a "medicine" under Regulation 1591.

You describe the operation of the item as follows:

"The Medtronic Endovascular Prosthesis ('Endovascular Prosthesis') is designed to provide a permanent alternative conduit for blood flow within the patient's vascular system which excludes the aneurysmal sac from blood flow and pressure. The Delivery Catheter allows endovascular placement of the Endovascular Prosthesis via either retrograde (femoral or iliac arteries) or antegrade (subclavian or axillary arteries) approaches.

"The device consists of three components:

1. The Endovascular Prosthesis: A polyester thin wall graft supported externally by self expanding nitinol stents.
2. The Delivery Catheter: The Endovascular Prosthesis is pre-loaded into the catheter. The Endovascular Prosthesis is delivered to the proper anatomical position with the Delivery Catheter and then deployed.
3. The Deployment Handle: Sold separately, the Deployment Handle facilitates deployment of the Prosthesis from the Delivery Catheter.

“The device is used in conjunction with the AneuRx Rapid-Trak Introduction Sheath, or other appropriately sized Introducer Sheath, which is supplied separately.

* * *

“The Endovascular Prosthesis is intended for use in patients with abdominal aortic or aorto-iliac aneurysms.

OPINION

A. Sales and Use Tax Generally.

In California, except where specifically exempted by statute, Revenue and Taxation Code Section 6051 imposes a sales tax, computed as a percentage of gross receipts, upon all retailers for the privilege of selling tangible personal property at retail in this state. (Unless otherwise stated, all statutory references are to the Revenue and Taxation Code.) “[I]t shall be presumed that all gross receipts are subject to tax until the contrary is established. The burden of proving that a sale of tangible personal property is not a sale at retail is upon the person who makes the sale ...” (§ 6091.) “Exemptions from taxation must be found in the statute.” (Market St. Ry. Co. v. Cal. St. Bd. of Equal. (1953) 137 Cal.App.2d 87, 96 [290 P.2d 201.]) “The taxpayer has the burden of showing that he clearly comes within the exemption.” (Standard Oil Co. v. St. Bd. of Equalization (1974) 39 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

B. Prescription Medicines.

Section 6369, interpreted and implemented by Title 18, California Code of Regulations, Section 1591, provides that sales of medicine, when prescribed and sold or furnished under certain conditions for the treatment of a human being, are exempt from sales or use tax. (Reg. 1591(a).) Subdivision(b)(1) defines “medicine” to “mean and include any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and which is commonly recognized as a substance or preparation intended for such use.” However, Regulation 1591(c)(2) adds that “medicines” do not include “articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof.” As a rule, then, items used to diagnose a condition or to apply medicine or treatment to the patient are not considered to be medicines.

Regulation 1591(b) does provide that certain items which might otherwise be considered as being devices, etc., are defined as "medicines." Regulation 1591(b)(2) includes articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body.

C. Tax Consequences to Cardiovascular Concepts.

You ask two questions: (1) would sales of the system be exempt from tax under Section 6369 and Regulation 1591; and (2) if not, would the sale of the Delivery Catheter itself be exempt from tax if it was billed separately from the other components?

As you describe it, the Endovascular Prosthesis itself is permanently implanted in the body to shore up the walls of the blood vessel into which it is inserted. The aneurysm is thus bypassed and the pressure on it relieved. We conclude that the Endovascular Prosthesis itself qualifies under Regulation 1591(b)(2) as a medicine the transfers of which are exempt from tax when performed in accordance with Regulation 1591(a). The Delivery System and the Deployment Handle are, however, used for inserting the Endovascular Prosthesis into position and do not remain with the body. Nor do they fit any other statutory exemption. The sales of the Delivery System and the Deployment handle are thus subject to tax. If all three items are sold together as a kit, a segregation is required to ascertain the correct measure of tax.

I hope the above discussion has answered your question. If you need anything further, please do not hesitate to write again.

Sincerely,

John L. Waid
Senior Tax Counsel

JLW:sr

cc: Sacramento District Administrator - KH